THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE COUNTY COMMISSION OF PUTNAM COUNTY,

Plaintiff,

v.

CIVIL ACTION NO. 3:18-cv-00350
JUDGE: _____

AMERISOURCEBERGEN DRUG CORPORATION;
CARDINAL HEALTH, INC.; CARDINAL HEALTH 110, LLC,
CARDINAL HEALTH 200, LLC,
McKESSON CORPORATION;
PURDUE PHARMA L.P., PURDUE PHARMA, INC.,
PURDUE PHARMACEUTICALS, L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMA MANUFACTURING, L.P.,
THE PURDUE FREDERICK COMPANY, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
PAR PHARMACEUTICAL, INC.,
ALLERGAN PLC; ALLERGAN USA, INC.,
WATSON LABORATORIES, INC.;
ACTAVIS LLC; ACTAVIS PHARMA, INC.;
MALLINCKRODT PLC and MALLINCKRODT LLC.,

Defendants.

COMPLAINT

Now comes the Plaintiff, The County Commission of Putnam County (hereinafter sometimes referred to as the "Putnam County Commission" or "Plaintiff"), by counsel, and for its Complaint against the Defendants alleges and avers as follows:

THE PARTIES

1. Plaintiff, The County Commission of Putnam County (hereinafter sometimes referred to as the "Putnam County Commission" or "Plaintiff"), is a West

Virginia corporation "which may sue and be sued, plead and be impleaded and contract and be contracted with" in its own name. *W. Va. Code* § 7-1-1(a) [2008]. A "political subdivision" of the State of West Virginia, neither an agency nor an agent of the State of West Virginia, the Putnam County Commission is responsible for both government and proprietary functions involving the superintendence and administration of the internal police and fiscal affairs of Putnam County, West Virginia. *W.Va. Code* §7-1-3. Among such functions are the providing of emergency ambulance services. W.Va. Code §7-15-4.

2. The Putnam County Commission is additionally charged with taking "other appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W.Va. Code § 7-1-3kk.

3. The Defendants, comprised of both manufacturers and distributors, are engaged collectively in the manufacture and/or distribution, promotion, sale and marketing of human prescription medications commonly known as opioids.

4. AMERISOURCEBERGEN DRUG CORPORATION, (hereinafter "AmerisourceBergen") is a Delaware corporation with a principal office address of 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. AmerisourceBergen is a pharmaceutical distributor that is registered with the West Virginia Board of Pharmacy as a wholesale distributor, and is authorized to do and does regularly do business in West Virginia, including Putnam County.

5. CARDINAL HEALTH, INC.; is an Ohio corporation, with a principal office address of 700 Cardinal Place, Dublin, Ohio 43017. Cardinal Health, Inc., specializes in distribution of pharmaceuticals and regularly does business in West Virginia, including Putnam County. Cardinal Health Inc., was previously registered with the West Virginia

Board of Pharmacy as a wholesale distributor. Numerous active wholesale distributor registrations still exist for "Cardinal Health."

6. CARDINAL HEALTH 110, LLC is a Delaware limited liability company in the business of wholesaling pharmaceuticals with a principal place office address of 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health 110, LLC, is authorized to do and does regularly do business in West Virginia, including Putnam County. Cardinal Health 110, LLC is a "registrant" and holder of multiple wholesale distributor licenses with the West Virginia Board of Pharmacy. Cardinal Health 110, LLC is a wholly owned subsidiary of Cardinal Health, Inc.

7. CARDINAL HEALTH 200, LLC is a Delaware limited liability company in the business of wholesaling pharmaceuticals with a principal place office address of 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health 200, LLC, is authorized to do and does regularly do business in West Virginia, including Putnam County. Cardinal Health 200, LLC is a "registrant" and holder of multiple wholesale distributor licenses with the West Virginia Board of Pharmacy. Cardinal Health 200, LLC is a wholly owned subsidiary of Cardinal Health, Inc., and member managed by Cardinal Health 110, LLC.

8. Hereinafter collectively, "Cardinal Health", CARDINAL HEALTH, INC.; "Cardinal Health." CARDINAL HEALTH 110, LLC and CARDINAL HEALTH 200, LLC, regularly do business in West Virginia, including Putnam County, manufacturing, promoting, selling and/or distributing hydrocodone.

9. McKESSON CORPORATION is a Delaware corporation with a principal office address of One Post Street, San Francisco, California 94104. McKesson Corporation is authorized to do and does regularly do business in West Virginia, including

Putnam County. McKesson Corporation is a "registrant" and holder of multiple wholesale distributor and miscellaneous licenses with the West Virginia Board of Pharmacy.

10. PURDUE PHARMA L.P. is a Delaware limited partnership with a principal office address of One Stamford Forum, Stamford, Connecticut 06901, that manufacturers and distributes pain management medication. Purdue Pharma, L.P. is a "registrant" with the West Virginia Board of Pharmacy holding multiple licenses as a manufacturer. Purdue Pharma L.P., is registered to do and does regularly do business in West Virginia, including Putnam County, identifying its General Partner as Purdue Pharma, Inc. PURDUE PHARMA, INC., is a New York corporation with its principal place of business located in Stamford, Connecticut.

11. PURDUE PHARMACEUTICALS, L.P., is a Delaware limited partnership with its principal place of business located in Stamford, Connecticut. Purdue Pharmaceuticals, L.P. is a "registrant" with the West Virginia Board of Pharmacy holding multiple licenses as a manufacturer and "miscellaneous" pharmaceutical activities. THE P.F. LABORATORIES, INC., is a New Jersey corporation with its principal place of business located in Stamford, Connecticut. Upon information and belief, P.F. Laboratories, Inc., manufacturers pharmaceuticals in Totawa, New Jersey that are distributed to markets in West Virginia, including Putnam County.

12. PURDUE PHARMA MANUFACTURING, L.P., is a Delaware limited partnership with a principal office address in Stamford, Connecticut. Purdue Pharma Manufacturing, L.P. is a "registrant" with the West Virginia Board of Pharmacy holding multiple licenses as a manufacturer and "miscellaneous" pharmaceutical activities. THE PURDUE FREDERICK COMPANY, INC., is a Delaware corporation with its principal place of business located in Stamford, Connecticut. Upon information and belief, The

Purdue Frederick Company, Inc., manufacturers and/or markets and/or distributes pharmaceuticals to markets in West Virginia, including Putnam County.

13. Hereinafter collectively, "Purdue", PURDUE PHARMA L.P., PURDUE PHARMA, INC., PURDUE PHARMACEUTICALS, L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMA MANUFACTURING, L.P., and THE PURDUE FREDERICK COMPANY, INC., regularly do business in West Virginia, including Putnam County. Purdue manufactures, promotes, sells and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER.

14. CEPHALON, INC. is a Delaware corporation with its principal place of business located in Frazer, Pennsylvania. Cephalon, Inc., was formerly a "registrant" with the West Virginia Board of Pharmacy, holding a license as a wholesale distributor. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with a principal office address of 1090 Horhsam Road, North Wales, Pennsylvania 19454. TEVA Pharmaceuticals USA, Inc., is a "registrant with the West Virginia Board of Pharmacy holding multiple licenses as a wholesale distributor and "miscellaneous" activities.

15. Upon information and belief, Teva Ltd. purchased Cephalon, Inc., in October of 2011. Teva USA is a wholly owned subsidiary of Teva Ltd. Teva USA is authorized to do and does regularly do business in West Virginia, including Putnam County. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to manufacture, market, promote, sell and distribute opioids such as Actiq and Fentora in the United States. Upon information and belief, Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA. Teva Ltd. and Teva USA hold out

the Cephalon products Actiq and Fentora to the public as Teva products. Upon information and belief, the FDA-approved prescribing information and medication guide distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Upon information and belief, Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo and Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

16. JOHNSON & JOHNSON is New Jersey corporation with a principal place of business located in New Brunswick, New Jersey. JANSSEN PHARMACEUTICALS, INC., (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., as well as Janssen Pharmaceutica, Inc.) is a Pennsylvania corporation with a principal office location of Titusville, New Jersey. NORAMCO, INC., is a Delaware corporation with principal office located in Wilmington, Delaware. Noramco, Inc., is a "registrant" with the West Virginia Board of Pharmacy, holding multiple licenses for "manufacturer" and "miscellaneous" activities. Noramco, Inc. was a wholly owned subsidiary of Johnston & Johnson until 2016, when they were acquired by SK Capital. Upon information and belief, Janssen Pharmaceuticals, Inc., is also a wholly owned subsidiary of Johnson & Johnson. as Johnson & Johnson regularly corresponds with the FDA on behalf of Janssen Pharmaceuticals, Inc., in relation to its products. Janssen Pharmaceuticals, Inc., Noramco, Inc. and Johnson & Johnson are referred to as "Janssen." Janssen and Noramco, Inc., manufacture, promote, sell and distribute drugs in the United States,

including the opioid Duragesic (fentanyl), and until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER.

17. ENDO HEALTH SOLUTIONS INC., is a Delaware corporation with a principal office location of Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC., is a Delaware corporation with a principal office address of 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals, Inc., is authorized to do and does regularly do business in West Virginia, including Putnam County. Endo Pharmaceuticals, Inc., is a "registrant" with the West Virginia Board of Pharmacy holding a license as a wholesale distributor. PAR PHARMACEUTICAL, INC., is a New York corporation with a principal office located in New York County, New York. Par Pharmaceutical, Inc., is a "registrant" with the West Virginia Board of Pharmacy, holding licenses as manufacturer, wholesale distributor and "miscellaneous" pharmaceutical activities.

18. Upon information and belief, Endo Pharmaceuticals, Inc., and Par Pharmaceutical, Inc., are wholly owned subsidiaries of Endo Health Solutions, Inc., which are collectively referred to herein as "Endo." Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, West Virginia and Putnam County.

19. Upon information and belief, in 2012, Watson Pharmaceuticals, Inc.[1], acquired Actavis, Inc., initially adopting the name Actavis, Inc., and later becoming Actavis PLC, in October 2013. Actavis, PLC, a public limited company incorporated in Ireland with its global headquarters located in Dublin, Ireland, and its administrative

[1] Watson Laboratories, Inc., was previously a "registrant" with the West Virginia Board of Pharmacy licensed as a wholesale distributor and "miscellaneous" pharmaceutical activities.

headquarters located in Parsippany-Troy Hill, New Jersey, changed its name to ALLERGAN PLC, on June 15, 2015, when it acquired Allergan PLC. However, the company's US and Canadian generics business continue to operate under the ACTAVIS name. In July 2015, ALLERGAN PLC announced the sale of its generics division to Teva Pharmaceuticals, Ltd. WATSON LABORATORIES, INC., is registered as a domestic Nevada corporation, Ohio corporation and Connecticut corporation. Upon information and belief, Watson Laboratories, Inc.'s principal executive office is located in Parisippany, New Jersey, and it was previously a "registrant" with the West Virginia Board of Pharmacy, holding a license as a wholesale distributor and "miscellaneous" pharmaceutical activities. Upon information and belief, Watson Laboratories, Inc., is a *wholly-owned subsidiary of* ALLERGAN PLC.

20. ACTAVIS PHARMA, INC. (f/k/a Watson Pharma, Inc..) is a Delaware corporation with a principal office address of 400 Interpace Parkway, Parisppany, New Jersey. Actavis Pharma, Inc., was is a "registrant" with the West Virginia Board of Pharmacy holding a license as a wholesale distributor and "miscellaneous" pharmaceutical activities. Actavis Pharma, Inc., is registered to do and does regularly do business in West Virginia, including Putnam County.

21. ALLERGAN USA, INC., is Delaware corporation with a principal office location of Irvine, California. Allergan USA, Inc., is a "registrant" with the West Virginia Board of Pharmacy currently holding license as a manufacturer and previously holding license as a wholesale distributor. Allergan USA, Inc., is registered to do and does regularly do business in West Virginia, including Putnam County. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

22. Upon information and belief, WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC., ALLERGAN USA, INC., and ACTAVIS LLC, are all owned by ALLERGAN PLC, which exercises control over the marketing and sale of opioid drugs in the United States, and ultimately profits from the sale of Allergan/Actavis/Watson products in Putnam County, West Virginia. Actavis PLLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Allergan USA, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively sometimes referred to herein as "Allergan." Upon information and belief, Allergan manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States.

23. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as "Mallinckrodt." Mallinckrodt manufactures, markets, and sells generic oxycodone in the United States, and ultimately profits from the sales in Putnam County, West Virginia.

STANDING, JURISDICTION & VENUE

24. Plaintiff has standing to recover damages incurred as a result of Defendants' action and omissions as it has suffered an injury-in-fact which is actual, concrete and particularized and which was proximately caused by the acts and omission of the Defendants. Plaintiff additionally has standing to bring claims under the federal RICO

statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

25. This Complaint was filed as an original action in the United States District Court for the Southern District of West Virginia. .

26. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

27. This Court has personal jurisdiction over Defendants because they conduct business in West Virginia, purposefully direct or directed their actions toward West Virginia, consented to be sued in West Virginia by registering an agent for service of process, consensually submitted to the jurisdiction of West Virginia when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with West Virginia necessary to constitutionally permit the Court to exercise jurisdiction.

28. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g.*, *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824,

*3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

29. Venue is proper in this District under Southern District of West Virginia pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. §§ 1391(b); § 1965(a).

30. Plaintiff does not bring any product liability claims or causes of action and does not seek compensatory damages for death, physical injury to person, or emotional distress. Claimant does not bring common law claims for property damage.

FACTS RELEVANT TO ALL COUNTS

31. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[2]

32. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[3]

33. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels.[4]

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[2] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[3] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

[4] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

34. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[5]

35. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[6]

36. The Centers for Disease Control and Prevention has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[7]

37. The societal costs of prescription drug abuse are "huge."[10]

38. Across the nation, local governments are struggling with the ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[11]

39. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and

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[5] *See* Califf et al., *supra* note 3.

[6] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[7] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

[10] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

[11] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

economic welfare."[12] The economic burden of prescription opioid misuse alone is $78.5 billion dollar a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[13]

40. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[14]

41. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[15]

42. In 2016, the President of the United States declared an opioid and heroin epidemic.[16]

43. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[17] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

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[12] Opioid Crisis, NIH.

[13] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

[14] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

[15] *See* Volkow & McLellan, *supra* note 1.

[16] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

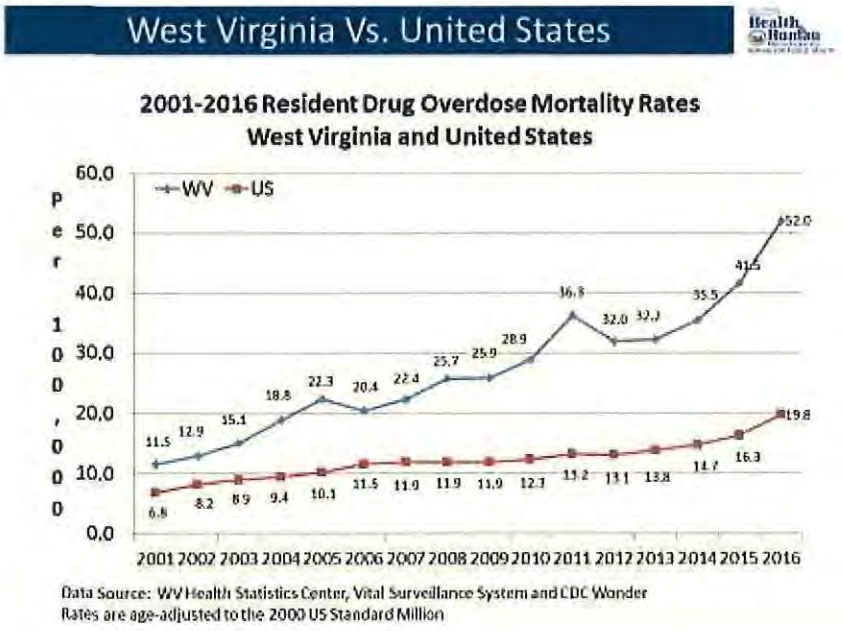
[17] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

44. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

WEST VIRGINIA'S OPIOID EPIDEMIC

45. West Virginia has been especially ravaged by the national opioid crisis.

46. In 2016, West Virginia had the highest overdose rate in the nation at 52 overdose deaths per 100,000 population, surpassing the next closest state, Ohio, by over 20%.

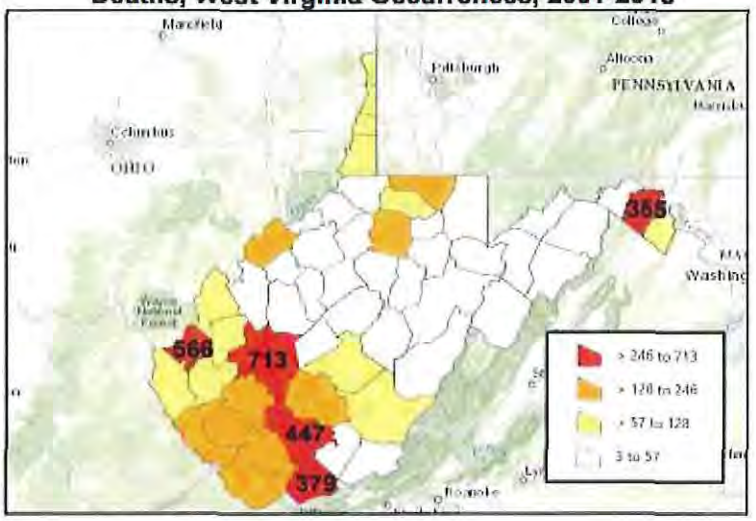


47. In 2014, the rate of opioid-related inpatient stays in West Virginia, per 100,00 of population, was 349.3, the 6th highest in the nation and 34% higher than the

national average. [18] The cumulative percentage change in the rate of opioid-related inpatient stays in West Virginia from 2009 to 2014, represented a 49.4% increase, more than double the national average.[19]

48. The opioid epidemic is particularly devastating in Plaintiff's Community of Putnam County.

Figure 7: County-Level Distribution of Opioid-Related Overdose Deaths, West Virginia Occurrences, 2001-2015



Data Source: WV Health Statistics Center, Vital Statistics System 2015 Preliminary Data

49. Plaintiff's Community is experiencing an excessive drug overdose rate[20] related to an excessive volume of prescription opiates[21] proximately caused by the wrongful conduct by the Defendants described and named herein.

50. The opioid epidemic did not happen by accident. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used

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[18] Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, *Statistical Brief #219, Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014,* https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

[19] *Id.*

[20] West Virginia Drug Overdose Historical Overview 2001-2015 WVDHHR Bureau for Public Health. Dhhr.wv.gov/oeps/disease/ob/documents/opioid/wv-drug-overdoses-2001-2015.pdf.

[21] *Id.*

short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

51. Each Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

52. The Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Defendants' claims.

53. The Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Defendants recruited for their support of their marketing messages, through unbranded marketing and industry-funded front groups and by deploying seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

54. Defendants' efforts have been hugely successful. Opioids are now the most prescribed class of drugs with sales in the United States exceeding $8 billion in revenue annually since 2009.[22] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[23]

55. This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids.

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[22] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, https://www. ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[23] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

56. The Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

57. The Defendants' direct marketing of opioids consisted of advertising campaigns touting the purported benefits of their branded drugs, such as the more than $14 million spent on medical journal advertising of opioids in 2011, triple that of 2001 spending.

58. Many of the Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

59. The Defendants also promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs, devoting massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Defendants spent more than $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. Detailing to doctors is effective; numerous studies

indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

60. The Defendants also purchased, manipulated and analyzed some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages, thus ensuring that their detailing to doctors is effective.

61. The Defendants also indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (*referred to hereinafter as "Front Groups"*).

62. The Defendants deceptively marketed opioids in the State of West Virginia and Plaintiff's Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

63. The Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and

objective source. The Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

64. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. Upon information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

65. The Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors, and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

66. In 2007, multiple States, including West Virginia, sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the

future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

67. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Defendants.

68. Dr. Portenoy appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[24]

[24] Good Morning America (ABC television broadcast Aug. 30, 2010).

69. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[25] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[26]

70. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the manufacturer Defendants (including nearly $2 million from Cephalon).

71. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

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[25] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[26] *Id.*

72. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Defendants and those under their influence and control.

73. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff's Community.[27]

74. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth

[27] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[28] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[29]

75. The Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Defendants.

76. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[30]

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[28] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

[29] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

[30] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015),

77. The most prominent of the manufacturing Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007, primarily from Endo and Purdue, until it closed its doors in May 2012,. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff's Community.

78. Even though APF held itself out as an independent patient advocacy organization, more than 80% of its operating budget came from pharmaceutical industry sources. Upon information and belief, by 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

79. APF often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors.

80. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to

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https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

APF's credibility as an objective and neutral third party, and the Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[31]

81. Another front group for the Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the manufacturer Defendants, the AAPM issued purported treatment guidelines, and sponsored and hosted medical education programs essential to the Defendants' deceptive marketing of chronic opioid therapy.

82. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended AAPM's annual event.

83. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

84. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain

[31] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[32]

85. At least fourteen of twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[33] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including manufacturer Defendants, made to the sponsoring organizations and committee members. The Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the manufacturer Defendants financial support to members of the panel.

86. The Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which

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[32] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

[33] *Id.*

began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the manufacturer Defendants determined would reduce prescribing.

87. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

88. Some illustrative examples of the manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[34]

b. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

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[34] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

c. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

d. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

e. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

f. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[35]

g. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[36]

89. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[37] The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that

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[35] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[36] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[37] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

"continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[38]

90. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[39]

91. Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Defendants misrepresented to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

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[38] *Id.* at 2, 25.

[39] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

92. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.[40] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[41]

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved

[40] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

[41] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

93. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by Purdue as a reason to push more opioid drugs onto already addicted patients.

94. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

95. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[42]

96. A fourth category of deceptive messaging regarding dangerous opioids is the Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, *spontaneous abortion and premature labor in pregnant women.*[43]

97. The Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[44]

98. A fifth category of false, deceptive, and unfair statements the Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without

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[42] *Id.* at 11.

[43] *Id.* at 26.

[44] APF, *Policymaker's Guide*, *supra* note 48, at 32.

added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Defendants' deceptive claims include:

a. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[45] This publication is still available online.

b. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

c. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[46]

d. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

e. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

f. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[47]

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[45] APF, *Treatment Options*, *supra* note 47, at 12.

[46] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

[47] APF, *Policymaker's Guide*, *supra* note 48, at 32.

g. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

h. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[48]

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[49]

99. Once again, the 2016 CDC Guideline reveals that the Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[50] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[51] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[52] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[53]

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[48] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).

[49] Brief of APF, *supra* note 49, at 9.

[50] 2016 CDC Guideline, *supra* note 50, at 22–23.

[51] *Id.* at 23–24.

[52] *Id.* at 21.

[53] *Id.* at 16.

100. The Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[54] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[55] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[56] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

101. To convince doctors and patients that opioids should be used to treat chronic pain, the Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally

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[54] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[55] *Id.* at 6.

[56] *Id.* at 6 n.21.

beneficial and less harmful than long-term opioid use.[57] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

102. Some illustrative examples of the Defendants' false claims are:

a. Upon information and belief, Allergan distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give

[57] *Id.* at 15.

[pain patients] a quality of life we deserve."[58] This publication is still available online.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[59] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[60] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

103. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

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[58] APF, *Treatment Options*, *supra* note 47.

[59] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

[60] APF, *Policymaker's Guide*, *supra* note 48, at 29.

104. In 2010, the FDA warned Allergan, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[61] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

105. The Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[62]

106. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not

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[61] Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

[62] 2016 CDC Guideline, *supra* note 50, at 12.

last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

107. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

108. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with

> dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[63]

109. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[64] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[65]

110. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions

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[63] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

[64] *See* U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[65] *Id.*

for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

111. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain but were also approved by the FDA for such uses.

112. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order

to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[66]

113. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

114. As a part of their deceptive marketing scheme, the Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including West Virginia and Putnam County. For example, the Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs but were less likely to be educated about treating pain

[66] Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

and the risks and benefits of opioids and therefore more likely to accept the Defendants' misrepresentations.

115. The Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

116. The Defendants made Materially Deceptive Statements and Concealed Materials Facts.

117. As alleged herein, the Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, while manufacturing, marketing, and selling prescription opioids. The Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

118. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

119. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

120. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

121. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

122. Defendant Allergan made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

FRAUDULENT CONCEALMENT.

123. The manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish

that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

124. At all times relevant to this Complaint, the manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not

disclose Endo's involvement. Other manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

125. Finally, the manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

UNLAWFUL DISTRIBUTION OF OPIOIDS.

126. The Defendants are required registrants under The Comprehensive Drug Abuse Prevention and Control Act of 1970, and more specifically as required by 21 U.S.C.A. § 822.

127. The Defendants owe a duty under federal and state law to "design and operate a system to disclose . . . suspicious orders of controlled substances" where "[s]uspicious order include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 CRF §1301.74(b) , accord, *WVCSR* §15-2-4.4.

128. Additionally, the Defendants are required registrants under the West Virginia Wholesale Drug Distribution Licensing Act of 1991, W.Va. Code §60A-8-1, et seq., and more specifically, WVCSR §15-2-3.1.

129. West Virginia law requires that all registrants "provide effective controls and procedures to guard against theft and diversion of controlled substances." WVCSR § 15-2-4.2.1.

130. Defendants were required by law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

131. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

132. Each Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

133. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

134. The opioid epidemic in West Virginia, including *inter alia* in Plaintiff's Community, remains an immediate hazard to public health and safety.

135. The opioid epidemic in Plaintiff's Community is a temporary and continuous public nuisance and remains unabated.

136. The Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

DEFENDANTS BREACHED THEIR DUTIES TO REPORT AND REFUSE TO FILL SUSPCIOUS ORDERS

137. Prescription opiates are a controlled substance and are categorized as "Schedule II" drugs under West Virginia law. *See.* W.Va. Code §60A-2-206. These "Schedule II" drugs are controlled substances with a "high potential for abuse" where "[a]buse of the substance may lead to severe psychic or physical dependence." W.Va. Code § 60A-2-205; *accord,* 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

138. West Virginia law does not differentiate between the duties of a manufacturer and distributor. The Defendants, as manufacturers, distributors, or dispensers of controlled substance within this West Virginia, were required to annually obtain a registration issued by the state board of pharmacy. *W.Va. Code* §60A-3-302. However, while only persons actually engaged in these activities are required to obtain a registration, excusing related or affiliated persons, such as stockholders or parent

corporations of manufacturers from registration, the plain language of the statute creates a very broad category of persons who are required to register. *WVSCR* §15-2-3.1.1.

139. The plain language of the West Virginia statute, resulted in the registration, over the years of Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Cardinal Health 110, LLC, Cardinal Health 200, LLC, McKesson Corporation, Purdue Pharma, L.P., Purdue Pharma Manufacturing, L.P., Purdue Pharmaceuticals, L.P., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Noramco, Inc., Endo Pharmaceuticals, Inc., Par Pharmaceuticals, Inc., Allergan USA, Inc., Actavis Pharma, Inc., and Watson Laboratories, Inc.

140. By virtue of the required registration, each Defendant did in fact, or should have by law, assumed a duty to comply with all monitoring, record keeping and security requirements imposed under the regulations adopted by the West Virginia Board of Pharmacy, creating a duty to monitor and detect suspicious orders of prescription opioids; investigate and refuse suspicious orders of prescription opioids; report suspicious orders of prescription opioids; and prevent the diversion of prescription opioids into illicit markets in the State of West Virginia and Putnam County.

141. Each Defendant engaged in manufacturing was required to register with the DEA to manufacture Schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . . .

21 USCA § 823(a)(1) (emphasis added).

142. As manufacturing registrants, Section 823 required these manufacturers to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)."

143. Each Defendant engaged in distribution activities was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Said Defendants were "registrants" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements are adopted and incorporated into West Virginia law. *WVCSR* §15-2-2.

144. Each Defendant engaged in distribution activities had an affirmative duty under federal and West Virginia law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

145. The West Virginia Board of Pharmacy requires that all registrants, both manufacturers and distributors alike, "shall provide effective controls and procedures to guard against theft and diversion of controlled substances." *WVCSR* §15-2-4.2.1.

146. Each registrant shall additionally "design and operate a system to disclose to the registrant suspicious orders of controlled substances." *WVCSR* §15-2-4.4. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal patter, and orders of unusual frequency." *WVCSR* §15-2-4.4. These suspicious orders must then be reported to the office of the West Virginia Board of Pharmacy. *Id.*

147. Federal regulations, incorporated by West Virginia law impose a non-delegable duty upon wholesale drug manufacturers and distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

148. In addition to reporting all suspicious orders, manufacturers and distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

149. Regulation of these prescription drugs was undertaken with the purpose of providing a closed system intended to reduce the widespread diversion from legitimate

channels into illicit markets, while providing the legitimate drug industry with a unified approach to narcotic drug control. *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

150. In a September 27, 2006, letter directed at wholesale distributors, the DEA cautioned that wholesale distributors are "one of the key components of the distribution chain. . . [For the] system . . .to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[67]

151. A similar DEA letter was also directed at distributors on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter reminds each distributor that in addition to reporting suspicious orders, they have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[68] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[69]

152. On December 27, 2007, a second letter was sent by the DEA to distributors reminding them not only of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant

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[67] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[68] Rannazzisi Letter, *supra* note 83, at 2.

[69] *Id.* at 2.

suspicious orders of controlled substances," but also to report these suspicious orders to the DEA Division Office or face the Revocation of Registration like was issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007).[70]. The DEA letter further explains:

> The regulation also requires that the registrant inform the local DEA Division [of the suspicious order] . . . The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.
>
> . . .
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[71]

153. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

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[70] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[71] *Id.*

154. The Defendants knew they were required to exercise "due diligence" to monitor, detect, and halt suspicious orders because industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." .[72]

155. Each of the Defendants manufactured for, distributed and/or sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Putnam County and/or to retailers from which Defendants knew or should have known prescription opioids were likely to be diverted to Putnam County.

156. The sheer volume of prescription opioid, including hydrocodone and/or oxycodone, being sold and distributed in the State of West Virginia and Putnam County, when compared to the population of the State of West Virginia would have put any reasonable drug manufacturer and/or distributor on notice that large volumes of these drug orders must have been diverted as the population of West Virginia could not medically consume the vast quantities of opioids being shipped into the State. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[73]

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[72] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

[73] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

157. Both the manufacturers and the distributors of these Schedule II drugs either had, or by law should have had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and prevent diversion. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1), of substances, including opioids, and for violating recordkeeping requirements.[74]

158. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

159. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Putnam County and the damages caused thereby.

160. The Defendants breach their duties by failing to among other things:

a. Failing to design and operate a system to maintain effective controls and disclose to the registrant suspicious orders of controlled substances;

b. Failing to use due diligence to meaningfully monitor, detect and investigate suspicious orders of prescription opiates originating from Putnam County, and/or in areas from which the Defendants knew opioids were likely to be diverted to Putnam County;

c. Failing to report suspicious orders originating from Putnam County, and/or in areas from which the Defendants knew opioids were likely to be diverted to Putnam County; and

[74] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

d. Unlawfully filling suspicious orders of unusual size and orders deviating substantially from a normal pattern and/or orders of unusual frequency in Putnam County and/or in areas from which the Defendants knew opioids were likely to be diverted to Putnam County.

161. The federal and West Virginia state laws at issue are public safety laws.

162. The Defendants' violations of public safety statutes constitute prima facie evidence of negligence under West Virginia law.

163. The distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates a reckless disregard for the health, safety and welfare of the citizens of Putnam County and justifies an award of punitive damages.

MISREPRESENTATION OF COMPLIANCE

164. The Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public.

165. Defendants have refused to recognize any duty beyond reporting suspicious orders and have repeatedly argued incorrect limitations regarding their actual legal duties. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors, inaccurately denying the legal duties that the wholesale drug industry has been intractably disobedient in performing, complaining they actually do not have or at minimum should not have any duty to investigate and try to halt suspicious orders, arguing that such requirements were infeasible. [75]

[75] Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4–5, *14, *22

166. The positions taken by the trade groups is emblematic of the position taken by the Defendants in an industry wide fruitless attempt to deny their legal obligations to prevent diversion of the dangerous drugs form which they profit.[76]

167. Wholesale distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders.[77] The Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[78] McKesson admitted that, during the relevant time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers."[79] As a result of these violations, McKesson's authority to distribute controlled substances would be partially suspended.[80]

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[76] *See* Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

[77] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

[78] *Id.* at 4.

[79] *Id.*

[80] *Id.* at 6.

168. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[81] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[82] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[83] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[84]

169. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

170. Because of the distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA

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[81] *Id.* at 4.

[82] *Id.*

[83] *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017)[hereinafter 2017 Settlement Agreement and Release] https://www.justice.gov/opa/press-release/file/928471/download.

[84] *See* 2017 Settlement Agreement and Release, *supra* note 112, at 6.